DEPARTMENT OF PUBLIC HEALTH
DETERMINATION OF NEED GUIDELINES FOR POSITRON EMISSION TOMOGRAPHY

November 24, 1998

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I. INTRODUCTION

The purpose of these guidelines is to review applications for Positron Emission Tomography (PET), a regulated service for which no guidelines currently exist. Pursuant to 105 CMR 100. 301(c) of the Determination of Need Regulations (Acceptance of Applications for Filing), Dana-Farber Cancer Institute has declared its intention to file an application for a PET scanner and requested that Determination of Need (DoN) guidelines be developed. These guidelines reflect the advances in the clinical application of PET since September 4, 1990, when Massachusetts General Hospital (MGH) filed a determination of need application for a PET scanner to provide clinical services. The application was approved January 25, 1994, providing MGH with the only PET scanner in the state. A 1991 National PET Utilization Forecast developed by the American Hospital Association predicted that in the short-term, the clinical application of PET would be concentrated in cardiology (64%), neurology and psychiatry (31%) and oncology (5%) with long term projections indicating the most growth in oncology at 13%. Currently, national estimates on the percentage of PET scans performed in oncology ranges from 60 to 100% depending on the focus of the service. This significant growth in oncology has been attributed to the new development of 18-FDG whole body imaging, and third-party payers coverage of certain types of PET scans.

Information used in the preparation of these guidelines was obtained from clinical PET guidelines developed by the states of Illinois, Michigan, Missouri, Tennessee, and Virginia; *July 31, 1998 Position Paper on Need for Additional Positron Emission Tomography Services in Massachusetts* by Dana-Farber Cancer Institute; *April 1991 Review and Assessment of Positron Emission Tomography* by Office of Health Planning, Rhode Island Department of Health; and January 25, 1991 *Report on Costs and Charges of PET Services to the Institute for Clinical PET* by Coopers & Lybrand, now PricewaterhouseCoopers. Information was also obtained from a review of the available literature, and discussions with professionals in the field, providers of PET services, and third-party payers, as well as staff of the manufacturers of PET scanners. The discussions presented below, on PET technology, clinical applications, and reimbursement, as well as those discussions provided within the text, provide the framework for development of these guidelines.

II. DESCRIPTION OF PET TECHNOLOGY

PET has been used in academic and research settings since the early 1970s. By 1991, 20 PET centers were performing clinical studies and 40 PET centers were conducting research nationally. The Institute for Clinical PET estimates that there are currently 85 PET centers nationwide with approximately 50% performing both clinical and research studies. The diffusion of PET into clinical practice has been slow compared with other new imaging methods such as computerized axial tomography (CT) and magnetic resonance imaging (MRI). This slow diffusion is attributable to several factors, the changing health care economy, the complexity and high cost of PET, the role of the U.S. Food and Drug Administration in regulating the radiopharmaceuticals that are produced and used on-site for PET, and the apparent slow pace at which the Health Care Financing Administration and other third-party payers are developing policies for reimbursing PET scans.

PET is a nuclear medicine technique which has been used extensively as a research tool in the investigation of human physiology and pathology for over a decade. Recent advances in PET make it possible to measure local tissue and organ function, providing new ways of investigating disease at a molecular level, even in the absence of anatomical abnormalities apparent on CT and MRI. PET has two clinically relevant characteristics that distinguish it from the more conventional imaging procedures of CT

and MRI. First, PET allows for the quantitative assessment of physiological function in the living human body. This is possible because PET detects small changes in the concentration of radioactively labeled tracers in tissues, providing important information on individual biochemical processes. Second, normal physiological compounds to which radionuclide components have been added are used in PET. In many cases, such analogues can be directly substituted into normal physiological pathways, permitting the function of an organ system to be imaged. These capabilities make PET a promising key to the understanding of many biological events caused by disease or pharmacologic intervention. Whereas CT and MRI scanning are sophisticated methods of analyzing human anatomy, PET scanning allows for direct measurement of physiological function.

A PET imaging service usually consists of a cyclotron to produce the radionuclide, a radiochemistry facility to incorporate the radionuclide into a biological compound, a PET scanner to measure the distribution of these radiopharmaceuticals or radiotracers within the body, and a computer for image reconstruction. Radiopharmaceuticals used in PET may be divided into blood flow-imaging agents, metabolic-imaging agents and drug receptor-imaging agents.

The major biologically active isotopes of interest in PET scanning are short-lived and therefore must be produced on-site or located within close geographic proximity of the PET facility. These isotopes include Carbon-11 (20.4 minute half-life), Nitrogen-13 (10.3 minute half-life), Oxygen-15 (2.04 minute half- life), and Fluorine-18 (110 minute half-life). A cyclotron is the most efficient device for production of these isotopes. Large amounts can be produced within 5 minutes to one hour. FDG-18 (Fluorine 18-labeled 2-fluoro- deoxyglucose), developed almost 10 years ago, has since become the most widely used radiopharmaceutical in the field of PET today. Its uptake in the brain, heart and tumor tissue reflects glucose metabolism. PET radiopharmaceuticals for myocardial imaging include N-13-ammonia and rubidium-82 which measure regional myocardial blood flow. FDG-18 is also used for myocardial studies because of its ability to measure regional myocardial glucose metabolism and thereby identify areas of viable myocardium. Oxygen-15 labeled tracers are used to measure blood flow, oxygen utilization, and blood volume in brain studies as well as measure blood flow in heart studies. Carbon-11 labeled amino acids are used to measure protein synthesis and tumor metabolism, and Carbon-11 labeled fatty acids to measure myocardial metabolism. Generators are another source of radionuclides and do not require an in-house cyclotron. There are two established generator systems that produce short-lived radionuclides: the strontium 82-rubidium and the germanium 68-gallium generators.

Once a radioisotope has been produced it must be introduced into a biologically active chemical which must be done quickly due to the short half-life of these isotopes and in a shielded enclosure due to the high levels of radioactivity involved in many of these syntheses. The resulting radiochemicals are labeled versions of biologically active chemicals while most compounds used in traditional nuclear medicine are compounds modified by the attachment of a heavy radioactive nucleus such as 123-iodine or 99m-technetium. Thus, PET radiochemicals directly trace biological processes when introduced in the body while those used for traditional nuclear medicine often only approximate the behavior of such molecules.

The physics of PET scanning is complex and is outside the scope of these guidelines. Suffice it to say, a description of PET scanning provided in Rhode Island's Office of Health Planning April 1991 report helps with understanding the process. A PET scan procedure begins by producing the particular radiopharmaceutical necessary to obtain the measurement of interest. The patient either inhales, ingests, or receives an injection of this compound. Because the radioisotope used in the PET scan is short-lived, the

amount of radiation exposure the patient receives is about the same as from two chest X-rays. These "labeled" molecules travel through the blood stream to the area being studied where they undergo a biochemical reaction as a part of the body's normal metabolism. The imaging camera or scanner is used to measure the concentration of this radioactivity and assesses biological and chemical reactions. These measurements are based on the fact that when a positron emitting radioisotope decays, a pair of photons or positrons are emitted. Photons or positrons are positively charged electrons. These photons have the same energy and are emitted at the same time in opposite directions. This is essentially different from traditional nuclear medical isotopes, which emit only a single, low-energy photon. The positrons bounce around very rapidly hitting electrons from neighboring atoms until they slow down (lose kinetic energy) and combine with a negative electron in a nuclear physics reaction. When this reaction occurs, small bursts of energy are released in the form of gamma rays. Highly sensitive time-synchronized pairs of radiation detectors, within the scanner that surrounds the patient, detect these gamma rays and a computer translates these signals into an image on a color video screen. The shading pattern of different areas in the organ pictured on the screen varies according to the amount of biochemical activity in each area. Computer technology and descriptive physiological models allow a three-dimensional image to be reconstructed and analyzed. The digital images created are, in essence, pictures of the intensity of count data in the region of interest. The reconstruction can be measured qualitatively, or the count data can provide a quantitative estimate of perfusion (in milliliters of fluid per gram tissue per minute) or metabolism (in milligrams of substrate per gram of tissue per minute).

III. CLINICAL APPLICATIONS

Several clinical applications of PET have been developed and utilized by clinicians in the diagnosis and treatment of patients. The procedure is performed primarily on an outpatient basis. The applications fall into four primary areas: cardiology, neurology, psychiatry, and oncology. A brief discussion of these applications is presented below.

1. Cardiology

The main clinical application of PET scans in cardiology is improving the management of patients with coronary artery disease (CAD), particularly in severe cases with significantly impaired ventricular function. The principal application of PET is defining whether or not an area of ischemic myocardium is viable (having or retaining the ability to contract) or infarcted. When a segment of myocardium becomes severely ischemic it ceases to contract, but remains alive and capable of returning to normal contractility if it is re-perfused. The normal myocardium gets 80% of its energy from aerobic metabolism of the substrates--predominantly fatty acids--but also glucose to a variable degree. As the muscle becomes ischemic it obtains energy increasingly through anaerobic (glycolytic) metabolism of glucose. PET scans can demonstrate this change in energy use by imaging with ^{11}C fatty acids and ^{18}FDG. In practice only ^{18}FDG is usually necessary, which may be combined with ^{13}N-ammonia to measure myocardial perfusion. Thus, ^{18}FDG/^{13}N-ammonia images of the ischemic heart will show decreased perfusion (^{13}N-ammonia) and decreased ^{18}FDG compared to a normal heart. In contrast, non-viable (infarcted) muscle will neither be perfused nor utilize glucose. This ability to identify viable, salvageable myocardium is particularly valuable in assessing the need for revascularisation procedures [(coronary artery by-pass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)].

Current techniques for differentiating viable hibernating from non-viable myocardium are poor. They include electrocardiogram (ECG) Q-waves, or wall abnormalities, on ultrasound or gated isotope scans (all

of which may be seen in severe ischaemia), or fixed thallium-210 perfusion defects. The latter has been shown seriously to underestimate viable myocardium, even with delayed imaging or re-injection techniques. PET scan has been able to predict the outcome of coronary artery surgery. Surgical revascularisation results in an improvement in wall movement in more that 80% of segments with glucose (^{18}FDG) uptake and low blood flow, whereas only 8% of those segments with matched impairment of glucose uptake and blood flow improved. PET scan will also correctly predict recovery of wall motion following surgery in regions of abnormal wall motion and Q-wave infarction. A perfusion and metabolism study of the heart is estimated to take an average of two hours.

2. Neurology

The brain has been the most intensively studied organ using PET techniques because it is metabolically very active and because early PET scanners were designed to accommodate only the head. Currently, electroencephalography (EEG), using both surface electrodes and depth electrodes implanted in the brain, is the neurosurgical procedure used most frequently to establish the presence and site of epileptic focus. Increasingly, PET scans are being used as a non-invasive way to provide the same information. The tracer most commonly used to study epilepsy using PET is ^{18}FDG. During a seizure metabolic activity at the focus increases, resulting in increased uptake of ^{18}FDG. During the interictal phase there is relative hypoperfusion and hypometabolism of the epileptic focus. It has been found that the interictal study is more useful than the ictal study in defining the focus, both because of the difficulty of achieving ictal studies and because generalized spread of the seizure may sometimes produce misleading information. Over 50% of seizure patients have normal CT or MRI studies.

PET can detect seizure foci in up to 80% of these patients, having excellent correlations with the results of depth electrode studies. PET is also used to diagnose infantile spasms, which may be neurologically devastating and may be associated with widespread or focal hypermetabolic abnormalities. Of 36 patients investigated in a recent study, ^{18}FDG identified a focus in 23, whereas CT/MRI identified only 10. Focal surgical resection resulted in cure and resumption of normal development in many of these cases. PET studies using $^{15}O_2$, $C^{15}O_2$ and ^{18}FDG have the potential for improving the management of stroke through early detection and the selection of therapy for early stroke, for example, thrombolytics and revascularisation. PET with ^{18}FDG has been used in diagnosing early onset of Huntington's disease and to predict the likelihood of asymptomatic individuals developing the disease later in life. There is evidence that PET with the use of radiopharmaceuticals can be used to differentiate types of ataxias, confirm the diagnosis of early or ambiguous cases of Parkinson's disease and dementia, and diagnosis of cerebral involvement with systemic lupus erythematosus.

3. Psychiatry

In the majority of patients with Alzheimer's disease, ^{18}FDG metabolic or perfusion PET studies show hypometabolic changes in the temporo-parietal regions with sparing at the auditory, visual and mortor cortex as well as subcortical structures. These abnormalities may be seen very early in the course of the disease when CT or MRI scans are normal and the clinical diagnosis is still only one of 'possible' Alzheimer's disease. In addition, PET scans can differentiate Alzheimer's disease from other types of dementia such as Pick's disease (fronto-temporal hypometabolism), Huntington's disease (striatal hypometabolism), and from pseudodementia--depression presenting as a cognitive abnormality. Other psychiatric applications of PET

include potential for diagnosis, monitoring and drug therapy control of schizophrenia, obsessive compulsive and affective disorders.

4. Oncology

Cancer cell metabolism is variably abnormal depending on cell type. There is often increased aerobic glycolysis and increased membrane transport of glucose with a close correlation between rate of glycolysis and growth rate. Not surprisingly, the tracer which is most commonly used in tumor imaging is ^{18}FDG, although other tracers such as ^{11}C-labelled amino acids and nucleosides such as thymidine have also been used in studies. Increased accumulation of these tracers has been found in primary brain tumors, breast cancer, head and neck tumors, colorectal cancers, thyroid, lung, sarcomas, lymphomas and melanomas. Extensive validation studies have evaluated the use of PET in the management of brain tumors. The clinical applications include diagnosing of cancer, the non-invasive staging of malignancy, assessing prognosis, and most importantly, distinguishing active recurrent tumor from post-radiotherapy scar tissue, a differentiation which may be impossible using conventional imaging methods.

A new development is the use of whole body ^{18}FDG tomography studies in cancer to detect the extent of primary and secondary metastatic disease with only one procedure. It has been generally estimated that it takes up to two hours to perform whole body ^{18}FDG oncology studies. The whole body FDG technique can be combined with whole body bone scans using ^{18}F in the ionic form to differentiate benign from malignant bone lesions. This has the potential to revolutionize the work up of many cancer patients. ^{18}FDG is also used for glioma staging. All high grade tumors have increased uptake of ^{18}FDG in the tumor compared with the surrounding brain, whereas less than 10% of low grade tumors have increased uptake. Using ^{18}FDG studies to predict the survival of patients, a significant correlation is found between glucose uptake and survival. The mean survival in patients with high glucose uptake is only five months, whereas in patients with low glucose uptake it can be up to 18 months. FDG has also been used to monitor the effects of chemotherapy, with response (lowering of tumor metabolic rates) being observed long before the tumor size is seen to decrease. ^{11}C-thymidine and methionine studies have also been shown to be good predictors of response to chemotherapy and are more sensitive and specific than FDG for the diagnosis of tumors. This is particularly the case with low grade tumors and after radiation therapy, when radiation necrosis may mask recurrent tumor.

The role of PET in the evaluation of patients with lung cancer has focused primarily on distinguishing benign from malignant solitary lung nodules, staging for mediastinal or distant metastasis at initial diagnosis, re-staging for recurrence, and monitoring the effectiveness of therapy by their ability to accumulate ^{18}FDG and ^{11}C- methionine. There is increased glucose and amino acid metabolism in malignant tumors, compared with non-malignant lesions which frequently look similar on conventional imaging. There is obvious attraction to this technique in the investigation of pulmonary nodules of unknown etiology and if this replaces biopsy, there could be a significant benefit. Another similar application is use of ^{18}FDG to differentiate recurrent tumor from benign scar in lung cancer patients who have already been treated. ^{18}FDG was found to be highly sensitive for recurrent lung carcinoma. However, due to false-positive results, the recommendation is made that FDG PET scans should be interpreted in conjunction with other anatomical imaging modalities such as chest CT or MRI.

PET scanning is being used in patients with suspected recurrent colorectal tumors using ^{18}FDG. The recurrent tumors show increased ^{18}FDG uptake, whereas ^{18}FDG is low in non-malignant masses. The

potential benefit in this group of patients is significant as conventional CT scanning is frequently difficult to interpret in recurrent disease. Labeled therapeutic agents such as ^{18}F-5FU have been used in patients with colorectal cancer (in particular with liver metastases) to assess whether there is tumor uptake and retention of the drug and its active metabolites. In this way it may become possible to specifically tailor the chemotherapeutic agent used to the individual patient to maximize response without the need for lengthy trials of treatment.

Clinical application of PET has shown promise in determining the best therapy for patients with breast cancer. Estrogen receptors can be labeled with ^{18}Fluoro-estradiol. A significant relationship has been shown between the uptake of this tracer and estrogen receptor density on biopsy. Local and distant metastases have been localized using both this technique and ^{18}FDG whole body imaging. A progesterone receptor analogue has also been synthesized. Since progesterone receptor uptake is thought to be related to response to hormonal therapy, the progesterone receptor activity may well prove to a more useful marker in determining the most effective treatment plan.

IV. REIMBURSEMENT

The Carriers and Coverage Issues Manual obtained from Health Care Financing Administration's (HCFA), Medicare Division, indicates that effective March 14, 1995, Medicare coverage included PET perfusion imaging of the heart for the diagnosis and management of patients with known or suspected coronary artery disease, using Food and Drug Administration (FDA) approved radiopharmaceutical rubidium 82 (Rb 82). Effective January 1, 1998, Medicare coverage was also extended to include PET imaging for characterization of solitary pulmonary nodules and initial staging of lung cancer using FDA approved ^{18}FDG. Reimbursement is conditioned on PET's ability to effect the management and treatment of patients with either suspected or demonstrated lung cancer.

Discussions with staff at the Division of Medical Assistance indicate that PET imaging is not a covered service under its benefit plans. Massachusetts Blue Cross and Blue Shield (BC/BS) covers FDG PET scans for patients with complex partial seizures. It also covers FDG PET scans to diagnose patients with solitary pulmonary nodule and to stage lung cancer. Consistent with HCFA regulations for Blue Care 65 patients, BC/BS covers rubidium PET scans for coronary artery disease.

Under the Food and Drug Administration Modernization Act of 1007, FDA has the authority to regulate radiopharmaceutical drug products used in PET imaging. Staff at FDA anticipates approval of additional radiopharmaceuticals, which will provide a significant advantage for future biologic imaging.

V. FACTORS FOR REVIEW

The following factors, based on the DoN Regulations, will be used to evaluate applications for a PET service.

FACTOR ONE: HEALTH PLANNING PROCESS

Standard: Planning shall be conducted through consultation and collaboration with health care providers, and other interested parties, and with state planning

agencies to ensure that the proposed project will not unnecessarily duplicate existing resources in the service area.

Measure 1: The applicant shall describe the planning activities involved with the project. The description shall include the date of each contact, the nature of each meeting, and the conclusion drawn.

Measure 2: If the applicant is a consortium of hospitals, one of the hospitals must be a tertiary teaching facility in the service area. The hospitals must submit a copy of a signed joint sharing agreement describing the responsibilities of each hospital, including a formal plan for the operation of the clinical and administrative functions related to the PET service,

Measure 2 (cont'd) patient management, personnel, medical records, financing capital and operating costs and reporting results to referring physicians. The agreement shall designate a single site at which the PET scanner service will be located. The signed joint-sharing agreement must be included in the application at the time it is filed.

Measure 3: If the applicant is a multi-institutional system, a tertiary teaching facility in the service area must be a participant in this system. The applicant must submit copies of the referral agreements with other hospitals agreeing to refer patients to the PET facility. The signed referral agreement must be included in the application at the time it is filed.

Measure 4: If the applicant is a single hospital, it must be affiliated with a tertiary teaching facility in the service area. Documentation of the tertiary teaching hospital's role in the planning of the proposed PET service must be included in the application. The applicant must provide copies of signed referral agreements with other facilities stating that those facilities will utilize the PET service by the referral of patients. The signed affiliation and referral agreements must be included in the application at the time it is filed.

Discussion

Clinical PET guidelines from other states emphasize multi-hospital coordination and interdisciplinary cooperation, recommending that in the review of applications for a new PET service preference will be given to applications filed by a consortium of hospitals or by hospitals in a multi-institutional system. The guidelines also recommend that these consortia or multi-institutional systems must include an hospital with a full range of tertiary services to ensure that appropriate care is available for patient treatment. The guidelines note that tertiary care hospitals also have the resources and the experience to evaluate the medical efficacy of the PET service.

The sharing of services is an important aspect of health care planning. It reduces the unnecessary duplication of services and costs to the health care system while promoting reasonable patient access to a

major new technology. Thus, the applicant is encouraged to form a consortium or participate in a multi-institutional system in the utilization and evaluation of the PET scanner. High quality services are most likely to be provided when the continuum between diagnostic and therapeutic services is well coordinated. Tertiary teaching hospitals provide this continuum. Therefore, an application for a new PET service must include affiliation with a tertiary teaching hospital in the service area.

FACTOR TWO: HEALTH CARE REQUIREMENTS FACTOR

Standard: PET technology shall be allocated so as to maximize its clinical utility to meet the health care requirements of the target population without duplication of services or adverse service consequences, or with the least such adverse consequences.

Measure 1: Planning for a PET service shall be on a statewide basis with a service area population of 1.6 million people.

Measure 2: The applicant proposing to establish a new PET service with a single body scanner shall demonstrate a projected minimum demand of 1,250 PET scans annually in its service area at the time the application is filed. The applicant must specify how these projections were developed, including a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make these projections.

Measure 3: Other data shall be presented to supplement the general demand analysis in Measure 1. These data may describe factors affecting demand that are inadequately accounted for or particular institutional characteristics deserving special attention.

Measure 4: In reviewing comparable applications for a PET new service, preference will be given to applicants that are part of a consortium or a multi-institutional system.

Measure 5: The applicant proposing an additional body PET scanner shall demonstrate justification based on the following:

(a) projections of a minimum of 1,250 scans annually for the additional PET scanner at the time the application is filed;

(b) the existing PET scanner as well as other PET scanners in the applicant's service area have been performing 1,250 scans annually for the past year at the time the application is filed;

(c) changing patterns of use and growth of demand; and

(d) demonstrated pattern of referrals out to other PET services due to overload.

Discussion

Consistent with the Department's policy on the allocation of new, and highly specialized technology, such as PET, the guidelines recommend the state as the planning area to ensure reasonable geographic access and reduce the potential for service duplication in the service area. The guidelines also recommend a service area with a population base of at least 1.6 million people to ensure that sufficient demand exists to support a single PET scanner.

The guidelines from other states as well as the literature report a statewide or regional planning area for a PET service. Some states' guidelines also recommend the service area population to support a PET service. Rhode Island recommends 1 million people, Virginia 1.5 million, and Missouri 2 million. The literature's report of 1.6 million people was determined reasonable, given the population density of Massachusetts, and was adopted by the guidelines.

Annual demand projections to establish a single PET scanner service also vary by state. For example, Michigan requires 1,600 PET equivalents (number of patient visits times a conversion factor of 1.6 PET equivalents per patient visit), Missouri 1,000 scans (the source of the projections were not discussed), Rhode Island 1,300 scans (based on 800 CAD, 360 epilepsy and 140 brain tumor cases), Tennessee 1,125 procedures (5 procedures per day times 225 working days per year), and Virginia, 1,500 PET scans (simplified, ratio of thallium stress tests to total number of inpatient and outpatient nuclear medicine procedures). According to Rhode Island's Office of Health Planning 1991 report, the American College of Nuclear Physicians and Society of Nuclear Medicine Task Force indicates that a typical clinical PET facility should be performing 6-12 procedures per day. The report states that assuming 10% down time, an average of 10 scans per day, and 225 working days per year, approximately 2,250 scans could be performed annually. The January 25, 1991 Coopers & Lybrand study, based on a national survey of 26 clinical PET facilities, states that according to Health Technology Trends most existing PET facilities were not operating at efficient levels (only 75% of capacity) based on imaging industry volume standards of an average of 4 scans per day or 1,460 scans per year.

The literature reports that a clinical PET facility becomes self-supporting at the level of approximately 6 reimbursable procedures per day during a 5-day week based on approximately one hour to perform a scan. Assuming 52 weeks per year, this translates into 1,560 scans annually. Another literature report indicates that consistent with the goal of cost-efficient, non-invasive screening, a clinical PET facility must be capable of accommodating patient throughput of 6 to 12 patients per day, during an 8-hour day (average 5 scans per day). This report indicates that a PET center must have strong representation in the key areas of cardiology, neurology, psychiatry and oncology.

Demand projections recommended by other states' guidelines and reported in the literature vary according to the perceived optimal operating capacity of a PET scanner. This capacity ranges from 1,000 to 2,250 scans annually. Obviously, these estimates were based on different assumptions about the average length of time it takes to perform a scan. Discussions with national providers of PET services seem to support this claim. They indicate that PET scanning varies from one hour for selective imaging (of the brain, chest, or abdomen) to about two hours for whole body imaging. Therefore, the guidelines recommend demand projections of 1,250 scans annually to initiate a PET service with a single body scanner based on a mix of whole body and selective imaging procedures, adjusting for the time differences in scanning. The

1,250 figure translates into 5 scans per day, 5 days per week, 50 weeks per year, allowing down time for maintenance, calibration and repairs.

The guidelines of other states also include criteria for PET service expansion and scanner replacement. Some of the criteria for service expansion were incorporated into these guidelines. Consistent with the Department's policy, determination of need approval is not required for PET scanner replacement.

FACTOR THREE: OPERATIONAL OBJECTIVES

Standard: **PET services shall be staffed to ensure quality of care and efficient use of resources.**

Measure 1: The PET service shall be under the direction of a physician who is board certified in nuclear medicine or nuclear radiology or trained and licensed in nuclear cardiology and has additional documented experience and training in PET technology including radiochemistry.

Measure 2: Additional PET service staff shall include at a minimum:

(a) 1 FTE radiochemist trained at the Ph.D. level in radiochemistry or radiopharmacy who also has a background in PET physics or radiochemistry and experience in radiopharmaceutical production, if the cyclotron is on-site;

(b) 1 FTE nuclear medicine technologist with training in cyclotron operation and radiopharmaceutical production, and who will work under direction and supervision of the medical director, if the cyclotron is on- site;

(c) 2 FTE radiological technologists with documented training in radiology, nuclear medicine, or MRI/CT scanning and who are able to provide support in the areas of PET imaging system operation, patient preparation for PET studies, and image analysis and processing;

(d) 2 part-time nuclear medicine physicians from the hospital's nuclear medicine department to share the responsibilities for interpreting PET studies;

(e) 1 FTE cyclotron maintenance engineer, if cyclotron is on-site;

(f) 1 FTE image processing laboratory supervisor; and

(g) administrative staff as shall be necessary to handle scheduling, billing and clerical functions.

Standard: **Certain services should be available to ensure the PET facility's capability to make a proper diagnosis in the most efficient and effective manner possible and that patients receive appropriate treatment consistent with the diagnosis.**

Measure 1: The applicant proposing to initiate a PET service shall have available, at the time the application is filed, the following diagnostic services and medical specialties:

(a) Diagnostic Services include nuclear medicine, SPECT (single photon emission tomography), CT (computer axial tomography), MRI (magnetic resonance imaging), cardiac catheterization, ultrasound, and diagnostic radiology.

(b) Medical Specialties include open heart surgery, thoracic surgery, cardiology, oncology, radiation oncology, neurology, neurosurgery, and psychiatry.

Measure 2: Since PET should complement other diagnostic modalities, the proposed PET facility should provide or make available all of the diagnostic services listed in Measure 1(a) above. If any of these services are not available on-site, the application must include, at the time it is filed, written contracts or agreements with hospital(s) for provision of these services.

Measure 3: The medical specialties listed in Measure 1 (b) above must be available either on-site through member hospitals in the case of a consortia or through agreements in the case of a multi-institutional system. If the applicant is not a member of a consortium or a participant in a multi-institutional system, the application must include, at the time it is filed, written contracts or agreements with hospital(s) for provision of these services.

Measure 4: Prior to operation of the PET facility, the applicant must develop a Clinical Oversight Committee to review criteria for clinical protocols, review appropriateness and quality of clinical scans, develop educational programs, and supervise data collection and evaluation activities generated by the facility or required by the Department. The Committee shall include, at a minimum:

(a) representatives from radiology, cardiology, neurology, and oncology;

(b) a physician representative from outside the sponsoring facility, if not represented by (a) above; and

(c) an additional representative from a tertiary teaching hospital

engaged in or knowledgeable about PET activities, if not represented by (a) or (b) above.

Measure 5: The applicant must state that it shall provide utilization data, clinical data, and reports of clinical efficacy in comparison to other forms of diagnostic modalities as requested by the Department.

Measure 6: The applicant must state its intention to schedule patients based on clinical protocols and must state that ability to pay shall not be considered in the acceptance of patients for scans.

Standard: **PET devices must be proven safe and effective for clinical use.**

Measure 1: Applicants must agree to purchase only PET equipment which has pre-market approval from and radiopharmaceuticals approved by the Food and Drug Administration.

Standard: **All PET facilities shall develop and describe training and education plans.**

Measure 1: The applicant must develop and describe plans for education and training of technicians and other personnel staffing the facility.

Measure 2: The applicant is required to offer educational opportunities for radiologists and other physicians or clinical investigators to become familiar with the general applications of PET. The applicant must describe such plans.

Discussion:

The operational objective of a PET facility is to provide high quality services to patients. High quality services are more likely to be provided by well trained and experienced staff, because of the complex nature of the service. The literature and guidelines from other states report that a PET service requires appropriately trained physicians in nuclear medicine familiar with the appropriate diagnostic use and interpretation of cross-sectional images on the anatomical region(s) to be examined; and that these physicians should also participate in evaluation of the efficacy of PET. They report that other members of the PET multidisciplinary team should include skilled personnel--radiologists, technologists, radio-pharmacists, chemists, engineers, physicists, and computer scientists, if the cyclotron is on-site. The staffing requirements recommended in these guidelines reflect reports from the literature, recommendations of other states' guidelines, and discussions with providers of PET services.

A Clinical Oversight Committee is a major component of quality control under these guidelines. The Committee is responsible for ensuring that a quality assurance system is developed to gather data to evaluate the efficacy of PET scans and conduct clinical appropriateness of the procedures on a regular basis.

PET complements other diagnostic modalities. Therefore, the applicant proposing to provide PET service should at the very least provide or have available those diagnostic imaging techniques for purposes of comparison. Comparative data of PET and other imaging modalities should be collected and made available to the Department upon request. Medical specialties are also included as a requirement because the clinical application of PET results in diagnoses that might require surgical procedures or other forms of treatment that are usually available only in tertiary care facilities. Having these services available, particularly on-site, will ensure continuity of care.

A further operational objective of a PET facility is to participate in data collection, evaluation and educational activities which further the general knowledge about PET's applications and its relationship to other existing diagnostic modalities. Providing opportunities for radiologists and other physicians who may be involved in PET services to be trained in the technology is of special concern to the Department and should be addressed by the applicant.

A PET facility should facilitate equal access of patients to the service regardless of the ability to pay or source of payment. Thus, applicants are required to maintain information by payer and non-payer sources to indicate the volume of care from each source provided annually. Such information should be made available to the Department upon request.

FACTOR FOUR: **STANDARDS COMPLIANCE**

Standard: **The applicant shall provide the appropriate written assurances that it is currently, or shall be at the time of initiation of the PET service, in compliance with all applicable standards of safety and operation imposed by law.**

Measure 1: The applicant shall submit certification of registration and its most recent letter of compliance from the Radiation Control Program, Massachusetts Department of Public Health.

Discussion

PET services are subject to regulation by state agencies. PET services are regulated to protect workers, patients, and the general public from the hazards of unnecessary exposure to radiation.

FACTOR FIVE: **REASONABLENESS OF EXPENDITURES AND COSTS**

Standard: **The PET facility service shall be equipped to ensure an acceptable quality of service delivery and shall be constructed and operated at the lowest reasonable cost.**

Measure 1: The PET facility shall have at least one (1) fixed body PET scanner, a cyclotron,

a radiochemistry facility, computers for image reconstruction, and appropriate ancillary equipment, as well as patient waiting and preparation rooms, rest rooms and other patient accommodations.

Measure 2: If the proposed PET facility does not have an on-site cyclotron, the applicant must provide in the application, at the time it is filed, a written contract or agreement demonstrating that a reliable supply of radiopharmaceuticals will be available to the proposed PET facility for the proposed uses.

Measure 3: The PET facility must be hospital-based with the following minimum space requirements:

(a) 600 to1,000 gross square feet (GSF) if located in existing space either in the nuclear medicine or radiology department and with no on-site cyclotron; or

(b) 3,000 to 4,500 gross square feet (GSF) if no pre-existing space exists and with a cyclotron on-site.

Measure 4: The applicant shall discuss in its application how the capital cost estimates presented in the application were derived, the size and type of the PET equipment it expects to purchase, and all related costs. The applicant shall also submit evidence showing that several manufacturers were consulted regarding equipment costs.

Measure 5: The applicant shall discuss in its application how the operating cost estimates presented in the application were derived. Applicants shall submit operating costs estimates based on the projected number of clinical scans for the service.

Measure 6: The applicant shall provide the following additional information: anticipated break-even point for the service; the proposed cost per procedure; and schedule of charges per procedure for all third-party payers.

Measure 7: The applicant shall present any projected cost savings, including substitution for other diagnostic modalities, which may accrue to the institution(s) as a result of the operation of the PET service.

Measure 8: The equity contribution shall be a minimum of 20% of the approved maximum capital expenditure.

Measure 9: The applicant shall provide all capital expenditures and operating costs data on the schedules presented in Factor Five of the Determination of Need Application Kit.

Discussion

A fixed body PET scanner is recommended since the literature reports, and discussions with PET providers and staff of PET manufacturers confirm, that the movement is from head to body scanners which offer more flexibility in the clinical indications for PET imaging. The literature reports possible configurations of a PET facility, hospital-based or freestanding, with or without an on-site cyclotron. The literature also reports space ranging from 1,500 to 2,000 gross square feet (GSF) if the PET service is located in an existing nuclear medicine department and 3,500 to 4,500 GSF if no pre-existing space exists.

Discussions with staff at G.E. Medical Systems and Siemens, manufacturers of PET scanners, indicate space ranging from 400 to 1,000 GSF if the PET service is located in existing space; depending on the size of the scanner and availability of shared space with other services. With a cyclotron on-site the staff recommends a minimum of 3,000 GSF. Discussions with several national PET providers indicate space requirements ranging from 600 to 1,535 GSF for a service with no on-site cyclotron and from 4,500 to 5,163 GSF for a service with a cyclotron on-site. With an on-site cyclotron weight is a significant consideration for a PET facility, since the space must be capable of supporting at least 120,000 pounds, a substantial weight that accounts not only for the self-shielded cyclotron, (if on-site) but also for the necessary ancillary equipment.

Given the wide variance in space requirements reported, the guidelines recommend 600-1,000 GSF for a PET facility, with no on-site cyclotron, to be located in existing space either in the nuclear medicine or radiology department where ancillary and support services might be shared. The 600-1,000 GSF incorporate the space requirements most frequently cited. The guidelines also recommend 3,000 to 4,500 GSF if no pre-existing space exists and with a cyclotron on-site to incorporate the recommendations reported in the literature and by staff of manufacturers. Consideration for a variance may be given when based on documented need and financial feasibility

These guidelines recommend a hospital as the appropriate site for a PET facility, since most tertiary care teaching hospitals already provide the diagnostic modalities and medical specialties required to support a PET facility and also has the resources and experience in evaluating the efficacy of diagnostic imaging techniques.

According to the literature, major equipment costs for a PET service range from $4 million to $6 million which include the scanner, cyclotron and radionuclide delivery system. Additional costs include ancillary equipment such as hot cells, surge protectors, monitoring equipment for radiation and environmental control, emergency drug cart equipment, roentgenogram processor, computer workstations, software and laser printer. Discussions with staff of G.E. Medical Systems and Siemens indicate total major equipment costs ranging from $2.5 million to $4.5 million (in today's dollars). These costs include the cost of a scanner ranging from $950,000 (lower end of the technology) to $2.7 million, and $1.5 to $1.9 million for a cyclotron. Additional costs include radiation safety devices for handling radioisotopes and quality control equipment to ensure the quality and reliability of radiopharmaceuticals. Sharing radiopharmaceuticals produced in a regional cyclotron among several facilities and use of generator produced radiopharmaceuticals are both potential methods to reduce costs. Depending on the imaging being performed, the relatively short-life of many isotopes requires that the cyclotron be at the same site of the PET scanner. Also, facilities relying solely on a generator are restricted to a limited range of clinical applications.

Estimates reported in the literature on the annual operating costs for a PET service range from $1 million to $1.5 million. The literature reports that for break-even support, the average cost of a clinical PET study at a cyclotron site ranges from $1,550 to $2,000. The 1991 Coopers & Lybrand's study, discussed earlier, reported an average annual operating cost of $1.4 million per facility, based on 26 clinical PET facilities nationwide. The average cost per procedure for these 26 clinical PET facilities was $1,716 including both facility costs and physician professional expense. The average cost ranged from $1,617 for a rubidium PET procedure to $1,749 for a cyclotron based PET procedure. PET procedures provided at the 18 hospital-based sites averaged $1,817 and at the 5 freestanding sites $2,188. The average cost per procedure at the "Other" 3 sites (not defined) was $1,257. The operating costs reported here were most likely based on 1991 or 1992 dollars.

FACTOR SIX: **FINANCIAL FEASIBILITY AND CAPABILITY**

Standard: **The PET facility shall be within the financial capability of the applicant.**

Measure 1: The applicant shall disclose all sources of revenue applicable to the project that may be available and shall provide information on the number of projected scans by third-party payers.

Measure 2: The applicant shall specifically make adequate provisions for free care of patients requiring PET scans, based on probable third-party reimbursement and on area providers' expectations regarding the need for free care. The applicant shall discuss those provisions in its application.

Discussion:

Schedules A through H of the DoN Application Kit, audited financial statements, and other supportive material should demonstrate that the applicant's financial position is strong enough to take on the proposed project.

FACTOR SEVEN: **RELATIVE MERIT**

Standard: **The proposed PET service, on balance, shall be superior to alternative and substitute methods for meeting the unforeseen health care requirements of the target population.**

Measure 1: The applicant shall document the alternatives considered in the development of this project. This documentation shall indicate that shared service arrangements, such as a consortium or multi-institutional arrangement with other hospitals, have been investigated and found to be less advantageous in terms of access, quality and efficiency of patient care, cost benefits and other factors.

Measure 2: The applicant shall document that other lower cost technology alternatives to PET

scanning have been investigated and found to be less advantageous in terms of access, quality and efficiency of patient care, cost benefits and other factors.

Discussion

In evaluating an application to initiate a new PET service or expand an existing service, the merits of the project will be considered in comparison to other alternatives. The applicant must describe alternatives to the proposed project considered and discuss why these alternatives were rejected. In discussing the relative merits of possible options, the applicant may present information pertaining to the relative cost, quality and efficiency of the accepted and rejected alternatives.

The applicant must demonstrate that the project will meet the requirements outlined in these guidelines. At a minimum, the applicant must demonstrate the ability to operate a PET service that will provide adequate patient access and a high standard of care, at a reasonable cost, to all those within its service area who are in need of the proposed service, regardless of ability to pay. Encouraging hospitals to participate in a shared service is also an important goal of these guidelines. Therefore, consortia or multi-institutional systems will be considered superior to alternative methods of meeting the projected demand. This does not mean, however, that the project with the most hospitals involved will necessarily be awarded the service.

Another articulated goal of these guidelines is to provide opportunities for physicians, especially radiologists, to become familiar with PET and receive training in the taking and interpreting of scans as appropriate. Issues of cost savings may be considered determinant factor(s) by the Department when considering the most appropriate way to increase capacity.

FACTOR EIGHT: ENVIRONMENTAL IMPACT

In most instances, no environmental notification form or report will be required pursuant to 301 CMR 10.32(3) promulgated by the Executive Office of Environmental Affairs pursuant to Massachusetts General Laws Chapter 30, Sections 61-62H.

FACTOR NINE: COMMUNITY HEALTH INITIATIVES

Standard: **The applicant shall contribute over a five-year period an amount reasonably related to the cost of the project, for the provision of primary, preventive, diagnostic and therapeutic health care services necessary for underserved populations in the project's service area.**

Measure 1: The applicant shall submit a plan to provide primary, preventive, diagnostic and therapeutic services in accordance with this factor including any community services and contributions currently provided by the applicant in its service area.

Measure 2: The applicant shall file reports (frequency, content and format to be agreed upon)

with the Program Director detailing compliance with its approved plan and, to the extent practicable, an evaluation of the health effects thereof.

Discussion

As part of an on-going effort to improve the health status of the public, the Department has established requirements for DoN applicants to develop and fund primary and preventive health programs as well as diagnostic and therapeutic services in the community. Such programs and services should be aimed at meeting otherwise unmet needs. The Department has published an Informational Bulletin on Community Health Initiatives (most current year available, 1995) which specifies the categories of services and programs that are needed. The applicant is advised to consult with the Department's Office of Healthy Communities, and Community Health Network Area(s) (CHNA) in its service area to ensure that the proposed service is consistent with the network's priorities. The proposal should, however, be reasonably related to the type of DoN project for which the applicant is filing. Information on the Bulletin and the contact person in the CHNA may be obtained from the Determination of Need Program.